

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: JOHNSON & JOHNSON)	
TALCUM POWDER PRODUCTS)	
MARKETING, SALES PRACTICES AND)	MDL Docket No. 2738
PRODUCTS LIABILITY LITIGATION)	

This Document Relates To All Cases

**DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT,
LLC'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO
EXCLUDE PLAINTIFFS' EXPERTS' OPINIONS REGARDING ALLEGED
HEAVY METALS AND FRAGRANCES IN JOHNSON'S BABY POWDER
AND SHOWER TO SHOWER**

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INTRODUCTION

Plaintiffs' experts seek to come to trial and tell jurors that talc-based Johnson's Baby Powder and Shower to Shower (the "Products") contain trace amounts of purportedly carcinogenic heavy metals (nickel, chromium and cobalt) and fragrances that cause, or contribute to causing, ovarian cancer. They seek to do so, however, with zero scientific evidence that any of the heavy metals or dozens of fragrances they identify has any relationship to ovarian cancer. Instead, their opinions are grounded in speculation and innuendo, precisely the sort of evidence that Rules 403 and 702 of the Federal Rules of Evidence are intended to exclude.¹ And despite having five years since defendants filed *Daubert* motions identifying these deficiencies, Drs. Carson, Zelikoff, Plunkett and Crowley have not amended their reports with updated citations or to respond to defendants' arguments.² This only serves to underscore the paucity of their opinions.

In her *Daubert* ruling, Chief Judge Wolfson only addressed heavy metals in a footnote, stating that Dr. Carson may testify as to his opinion that "it is *plausible*

¹ This motion addresses opinions related to heavy metals and fragrances that are proffered by the following experts: Arch Carson, Daniel Clarke-Pearson, Robert Cook, Michele Cote, Michael Crowley, Sarah Kane, Mark Krekeler, Shawn Levy, Anne McTiernan, Patricia Moorman, Laura Plunkett, Jack Siemiatycki, William Sage, Sonal Singh, Ellen Blair Smith, Rebecca Smith-Bindman, Judith Wolf and Judith Zelikoff.

² Dr. Plunkett amended her report on unrelated topics.

that, as carcinogens, these heavy metals may cause ovarian cancer with respect to his Bradford Hill analysis only. To the extent Defendants take issue with that opinion, they may cross-examine Dr. Carson on that basis.” *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Litig.*, 509 F. Supp. 3d 116, 172 n.39 (D.N.J. 2020). This was not a fulsome *Daubert* analysis, and the Court did not address any other experts’ opinions on this topic.³ The first *Daubert* ruling did not address fragrances at all.

This motion is appropriate pursuant to the Court’s Order dated April 30, 2024, because: (1) Judge Wolfson’s ruling did not contain any analysis of plaintiffs’ experts’ opinions on fragrances; (2) Judge Wolfson only addressed heavy metals in passing in a short footnote; (3) Rule 702 has been amended to make clear that questions of reliability go to admissibility, not weight; (4) Judge Wolfson did not address any experts’ qualifications to address heavy metals; and (5) additional experts are now seeking to offer these opinions (in large part by parroting each other).

³ At the beginning of her lengthy opinion, Chief Judge Wolfson also held that “the reasoning in this Court’s Opinion, applies with equal force to the remainder of the pending *Daubert* motions.” *In re Johnson & Johnson*, 509 F. Supp. 3d at 128-29.

BACKGROUND

A. Heavy Metals

Talc is a mineral derived from metamorphic deposits.⁴ Each talc mine “has its own character.”⁵ Several plaintiffs’ experts claim that the Products contain various heavy metals that contribute to their purported carcinogenicity.⁶ In forming their opinions that the Products contain heavy metals, these experts rely primarily on documents provided by plaintiffs’ counsel.⁷ Notably, Dr. Krekeler conceded that the selected documents provided by plaintiffs’ counsel may have contained testing results that were taken *not* from the talc ore used to create the Products, but instead, from the surrounding rock to demarcate the areas of ore that were *not* suitable for mining.⁸ In addition, several plaintiffs’ experts conceded that

⁴ (Rep. of Mark Krekeler (“Krekeler Rep.”) at 2, Nov. 16, 2018 (Ex. 1 to Decl. of Jessica Davidson (“Davidson Decl.”)).)

⁵ (*Id.* at 5.)

⁶ (*See* Krekeler Rep. at 7-8; Rep. of Robert B. Cook (“Cook Rep.”) at 36, Nov. 16, 2018 (Ex. 2 to Davidson Decl.); Rep. of Judith Zelikoff (“Zelikoff Rep.”) at 11, Nov. 16, 2018 (Ex. 3 to Davidson Decl.); 3d Am. Rep. of Laura M. Plunkett (“Plunkett 3d Am. Rep.”) ¶ 36, May 28, 2024 (Ex. 4 to Davidson Decl.); Rep. of Arch Carson (“Carson Rep.”) at 5-6, Nov. 16, 2018 (Ex. 5 to Davidson Decl.).)

⁷ (*See, e.g.*, Dep. of Mark Krekeler (“1/25/19 Krekeler Dep.”) 30:7-9, Jan. 25, 2019 (Ex. 6 to Davidson Decl.); Dep. of Robert Cook (“1/30/19 Cook Dep.”) 34:16-20, Jan. 30, 2019 (Ex. 7 to Davidson Decl.); Dep. of Judith Zelikoff (“1/21/19 Zelikoff Dep.”) 292:1-6, Jan. 21, 2019 (Ex. 8 to Davidson Decl.).)

⁸ (1/25/19 Krekeler Dep. 147:22-25, 150:11-17, 152:22-153:9.)

they had no way of knowing how much, if any, metal ultimately ended up in the Products.⁹

None of Plaintiffs' experts was able to identify any scientific link between heavy metal exposure and ovarian cancer. For example, Dr. Zelikoff conceded at her deposition that she is not aware of any studies that suggest that exposure to heavy metals can cause inflammation in the ovaries.¹⁰ Further, none of the studies Dr. Zelikoff cites in her report suggests that exposure to heavy metals increases the risk for ovarian cancer.¹¹ And while plaintiffs' experts acknowledge that the "dose as well as frequency, duration, time of exposure" all "contribute to the toxicity of an agent,"¹² none of plaintiffs' experts addresses the threshold at which exposure to chromium, cobalt or nickel induces carcinogenesis or has any effect on human health. Nor did any of plaintiffs' experts make any effort to analyze the amount of exposure to heavy metals a woman would incur by using the Products.¹³

⁹ (*Id.* 277:24-278:5; Dep. of Arch Carson ("1/19/19 Carson Dep.") 176:5-10, 177:20-24, Jan. 19, 2019 (Ex. 9 to Davidson Decl.); 1/21/19 Zelikoff Dep. 271:18-272:2).)

¹⁰ (1/21/19 Zelikoff Dep. 291:14-24, 313:21-314:3.)

¹¹ (*Id.* 282:2-8.)

¹² (*Id.* 262:6-15; *see also* Dep. of Laura M. Plunkett ("12/19/18 Plunkett Dep.") 234:20-23, Dec. 19, 2018 (Ex. 10 to Davidson Decl.) (agreeing that dose is important to determine risk).)

¹³ (*See, e.g.*, 12/19/18 Plunkett Dep. 263:15-264:3 (explaining that she has "not done a – a calculation of a potential dose with perineal application for any of the heavy metals"); 1/19/19 Carson Dep. 171:1-21 (admitting that he does not know
(*cont'd*)

B. Fragrances

Johnson's Baby Powder contains a mixture of 141 fragrance ingredients.¹⁴ By weight, fragrances constitute just 0.22 percent of Johnson's Baby Powder, with the remaining 99.78 percent of the product consisting of talc.¹⁵ Shower to Shower contains a fragrance mixture comprised of 53 fragrances.¹⁶ By weight, fragrances constitute 0.55 percent of Shower to Shower, with the remaining 99.45 percent of the product consisting of talc, cornstarch, baking soda and calcium hydroxyapatite.¹⁷

Plaintiffs' experts suggest that these added fragrances contribute to the alleged carcinogenicity of the Products. In support of this claim, plaintiffs primarily offer the opinions of Michael Crowley—the president of Theridian Technologies, LLC, a pharmaceutical development consulting firm that he established in March 2009.¹⁸ Dr. Crowley has never written on the topic of

the amount of exposure to heavy metals that results from talc use and stating that it would be “useful to factor in the amount if the amount is known”).)

¹⁴ (Rep. of Michael M. Crowley (“Crowley Rep.”) at 11, Nov. 12, 2018 (Ex. 11 to Davidson Decl.).)

¹⁵ (See JNJALC000891091 (Ex. 12 to Davidson Decl.).)

¹⁶ (Crowley Rep. at 11.)

¹⁷ (See JNJALC001021615 (Ex. 13 to Davidson Decl.).)

¹⁸ (Crowley Rep. at 14.)

fragrance chemicals.¹⁹ Further, Dr. Crowley admitted at his deposition that there are no human studies linking *any* of the fragrances in the Products to ovarian cancer in humans.²⁰ And although Dr. Crowley agrees that “poisons” generally have a “dose-and-exposure relationship,”²¹ he made no effort to determine whether a consumer would actually be exposed to harmful levels of fragrances by using the Products.²²

ARGUMENT

I. NEARLY ALL OF PLAINTIFFS’ EXPERTS ARE UNQUALIFIED TO OPINE ON HEAVY METALS OR FRAGRANCES AND MERELY PARROT OTHER EXPERTS’ OPINIONS.

“Before an expert witness may offer an opinion pursuant to Rule 702, [s]he must first be qualified by virtue of specialized expertise.” *Ortiz v. Yale Materials Handling Corp.*, No. 03-3657FLW, 2005 WL 2044923, at *3 (D.N.J. Aug. 24, 2005) (quoting *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000)).

Allowing an expert to offer an opinion in an area where he or she lacks expertise “would not be responsible” science. *See, e.g., TK-7 Corp. v. Est. of Barbouti*, 993 F.2d 722, 732, 735 (10th Cir. 1993). “If an expert’s area of experience ‘is adjacent

¹⁹ (Dep. of Michael Crowley, Ph.D. (“1/4/19 Crowley Dep.”) 65:5-8, Jan. 4, 2019 (Ex. 14 to Davidson Decl.).)

²⁰ (*Id.* 114:22-115:6; *see also id.* 185:4-8, 195:21-196:18.)

²¹ (*Id.* 129:5-6.)

²² (*Id.* 107:21-108:5.)

to, but not actually encompassing, the subject matter of h[er] testimony, [s]he may be deemed unqualified.” *D & D Assocs., Inc. v. Bd. of Educ. of N. Plainfield*, No. Civ.A. 03-1026(MLC), 2006 WL 755984, at *3 (D.N.J. Mar. 20, 2006) (citation omitted). An “expert’s” inability to correctly answer basic questions and explain her opinions at her deposition is a telltale sign that the witness “is not competent to offer testimony to the jury on such matters.” *Dreyer v. Ryder Auto. Carrier Grp., Inc.*, 367 F. Supp. 2d 413, 428 (W.D.N.Y. 2005) (“Proctor’s inability to explain, within the relatively flexible confines of a pretrial deposition of a proposed expert witness, how the good engineering practices referred to by Proctor would be applied” to the facts of the case “demonstrates Proctor lacks competency to assist the jury in understanding the issues.”).

In addition, although an expert may rely upon another expert’s opinion in formulating her own views, an “[e]xpert[] may not simply ‘parrot’ the ideas of other experts and should not ‘become the mouthpiece of the witness on whose statements the expert purports to base his opinion.’” *Torain v. City of Philadelphia*, No. 14-1643, 2023 WL 174952, at *5 (E.D. Pa. Jan. 12, 2023) (citation omitted); *see also Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 612-14 (7th Cir. 2002) (stating that an expert “is not permitted to be the mouthpiece of a scientist in a different specialty”). This is so because the Federal Rules of Evidence “contemplate[] that a testifying expert can ‘validate the facts, data and opinions he

relied upon . . . and be subject to cross-examination on them.”” *Muhsin v. Pac. Cycle, Inc.*, No. 2010-060, 2012 WL 2062396, at *4, *8 (D.V.I. June 8, 2012) (citation omitted); *see also Member Servs., Inc. v. Sec. Mut. Life Ins. Co. of N.Y.*, No. 06-1164, 2010 WL 3907489, at *27 (N.D.N.Y. Sept. 30, 2010) (“While an expert may rely upon another expert to form an opinion under Rule 703, an expert may not merely recite another expert’s opinion as his own.”).

As explained below, plaintiffs’ experts’ opinions regarding heavy metals and fragrances outstrip their relevant expertise and amount to improper parroting of other witnesses’ conclusions.

A. Heavy Metals

Qualifications. Drs. Cook and Krekeler, who hold PhDs in minerology, were primarily asked to opine on mining processes—i.e., the subject of their background and experience. Although they also seek to testify that the heavy metals at issue are human carcinogens, they have zero expertise in biology or medicine and expressly disclaimed having the requisite credentials to weigh in on these specialized topics.²³

Similarly, 12 of plaintiffs’ epidemiology, gynecologic oncology, pathology and genetics experts each devote a few sentences buried in their otherwise lengthy

²³ (1/25/19 Krekeler Dep. 25:6-22; 1/30/19 Cook Dep. 70:12-71:4, 96:5-8, 96:20-97:2, 221:14-18, 224:8-23, 226:7-19.)

reports to the purported opinion that heavy metals are present in the Products and that these substances cause ovarian cancer. But these experts also lack independent knowledge and expertise in this area and performed no expert analysis of their own on this subject.²⁴

For example, Dr. Wolf—a gynecologist/oncologist—testified that she relied on only the deposition exhibit provided by plaintiffs and plaintiffs’ other experts for her opinion that heavy metals are present in talc and did not perform a data analysis to support an opinion that heavy metals are capable of causing ovarian

²⁴ These experts include Drs. Clarke-Pearson, Cote, Kane, Levy, McTiernan, Moorman, Siemiatycki, Sage, Singh, Smith, Smith-Bindman, and Wolf. (*See* 3d Am. Rep. of Daniel L. Clarke-Pearson (“Clarke-Pearson 3d Am. Rep.”) at 7-8, 13, May 28, 2024 (Ex. 15 to Davidson Decl.); Am. Rep. of Michele L. Cote (“Cote Am. Rep.”) at 11-12, 38-39, May 28, 2024 (Ex. 16 to Davidson Decl.); Rep. of Sarah E. Kane (“Kane Rep.”) at 5-6, 29, 36, Nov. 15, 2018 (Ex. 17 to Davidson Decl.); 2d Am. Rep. of Shawn Levy (“Levy 2d Am. Rep.”) at 18-20, May 28, 2024 (Ex. 18 to Davidson Decl.); 3d Am. Rep. of Anne McTiernan (“McTiernan 3d Am. Rep.”) at 10, 76-80, May 28, 2024 (Ex. 19 to Davidson Decl.); Rep. of Patricia G. Moorman (“Moorman Rep.”) at 35, Nov. 16, 2018 (Ex. 20 to Davidson Decl.); Am. Rep. of William Sage (“Sage Am. Rep.”) at 6-7, 27-28, Nov. 15, 2023 (Ex. 21 to Davidson Decl.); 3d Am. Rep. of Jack Siemiatycki (“Siemiatycki 3d Am. Rep.”) at 27-28, 71-72, May 27, 2024 (Ex. 22 to Davidson Decl.); Rep. of Sonal Singh (“Singh Rep.”) at 16, 60, Nov. 16, 2018 (Ex. 23 to Davidson Decl.); Rep. of Ellen Blair Smith (“Smith Rep.”) at 19, 21-22, Nov. 16, 2018 (Ex. 24 to Davidson Decl.); 3d Am. Rep. of Rebecca Smith-Bindman (“Smith-Bindman 3d Am. Rep.”) at 4, 11, 15, 36, May 28, 2024 (Ex. 25 to Davidson Decl.); 3d Am. Rep. of Judith Wolf (“Wolf 3d Am. Rep.”) at 11-12, 20, May 28, 2024 (Ex. 26 to Davidson Decl.).)

cancer.²⁵ Further, Dr. Wolf was also entirely unfamiliar with the fact that these metals are essential nutrients in the human body and/or contained in vitamins, or what role they play in the human body, betraying her lack of expertise.²⁶

Dr. McTiernan's epidemiological report asserts that "based on the scientific literature and testing results, it is my opinion that the presence of . . . heavy metals . . . are all biologically plausible explanations for talcum powder products causing ovarian cancer."²⁷ At her deposition, however, she testified that she has no "evidence one way or the other" as to whether the Products contain any heavy metals and "did not look at that."²⁸ She further testified that as an epidemiologist, testing of the Products for heavy metals "is not in my area of expertise."²⁹

Dr. Cote, an epidemiologist, offers the conclusory opinion that "there is evidence that talc contains heavy metals that are known to be carcinogenic."³⁰ While she acknowledged that "a comprehensive review [of a specific topic] should be undertaken before entering an opinion," she admitted that she "did not do a

²⁵ (Dep. of Judith K. Wolf ("1/7/19 Wolf Dep.") 373:8-374:2, 400:22-401:17, Jan. 7, 2019 (Ex. 27 to Davidson Decl.).)

²⁶ (*Id.* 431:19-435:24.)

²⁷ (McTiernan 3d Am. Rep. at 10, 76-77, 88.)

²⁸ (Dep. of Anne McTiernan ("1/28/19 McTiernan Dep.") 270:20-272:10, Jan. 28, 2019 (Ex. 28 to Davidson Decl.).)

²⁹ (Dep. of Anne McTiernan ("8/19/21 McTiernan Dep.") 115:17-116:5, Aug. 19, 2021 (Ex. 29 to Davidson Decl.).)

³⁰ (Cote Am. Rep. at 11.)

systematic review of heavy metal in talc powder” and was not aware of any study substantiating the theory that trace amounts of heavy metals cause ovarian cancer.³¹

Dr. Sage—who primarily addresses regulatory issues—similarly purports to opine that the Products “have also been shown to contain nickel, chromium, and cobalt,” and these substances are carcinogenic or possibly carcinogenic “according to the IARC.”³² But when asked if he reviewed the IARC monographs on heavy metals, Dr. Sage conceded that he had not done so “in any detail and perhaps not at all.”³³ Dr. Sage also testified that he did not perform an independent assessment on whether heavy metals exist in the Products, and as to the exhibit he cites in his report supposedly showing that these metals exist in the Products, plaintiffs provided it to him and he only looked at it “[i]n passing,” doesn’t “think [he] spent much time looking at [it],” and doesn’t know precisely what it is or who prepared

³¹ (Dep. of Michele L. Cote (“3/21/24 Cote Dep.”) 110:25-112:2, 142:24-143:4, Mar. 21, 2024 (Ex. 30 to Davidson Decl.)) Similarly, Dr. Smith, a gynecological oncologist, used nearly identical sentences to Dr. Sage and other experts to describe the supposed presence of heavy metals in talc and their carcinogenicity (Smith Rep. at 19), but testified that she did not perform a comprehensive scientific review of medical or scientific literature related to heavy metals that an expert should perform before offering an opinion (Dep. of Ellen Blair Smith (“1/9/19 Smith Dep.”) 59:20-60:2, 61:3-14, Jan. 9, 2019 (Ex. 31 to Davidson Decl.)).

³² (Sage Am. Rep. at 2, 6.)

³³ (Dep. of William M. Sage (“9/23/21 Sage Dep.”) 294:20-295:2, Sept. 23, 2021 (Ex. 32 to Davidson Decl.))

it.³⁴ Dr. Smith-Bindman, an epidemiologist, curiously used almost identical language to Dr. Sage and other experts to express her opinion that talc contains heavy metals that are carcinogenic, citing the same exhibit and the IARC.³⁵ However, Dr. Smith-Bindman made clear that she is not an expert in understanding reports on the concentration of metals in talc.³⁶

Dr. Siemiatycki, an epidemiologist, states that “[a]mong the metals detected in talcum powder products are some which are recognized carcinogens, namely nickel and chromium.”³⁷ When asked whether he is offering an opinion on heavy metals, Dr. Siemiatycki testified: “I have read references to the . . . detection of metals in talc products. I -- I can’t say. It[’s] certainly not something that I’m relying upon for any opinions about talc, but it’s something that I have read.”³⁸

Parroting. In light of these experts’ lack of expertise and independent

³⁴ (9/23/21 Sage Dep. 291:4-295:2.) Dr. Levy, a geneticist, opines that he has seen evidence that the Products contain heavy metals (Levy 2d Am. Rep. at 18), citing the same exhibit as other experts, but otherwise testified that such reference is just background and he did not perform any separate analysis as to heavy metals. (Dep. of Shawn Levy (“5/8/24 Levy Dep.”) 121:16-123:15, 126:22-128:6, May 8, 2024 (Ex. 33 to Davidson Decl.).)

³⁵ (Smith-Bindman 3d Am. Rep. at 4.)

³⁶ (Dep. of Rebecca Smith-Bindman (“2/7/19 Smith-Bindman Dep.”) 139:7-21, Feb. 7, 2019 (Ex. 34 to Davidson Decl.).)

³⁷ (Siemiatycki 3d Am. Rep. at 27, 71.)

³⁸ (Dep. of Jack Siemiatycki (“3/27/24 Siemiatycki Dep.”) 55:16-56:7, Mar. 27, 2024 (Ex. 35 to Davidson Decl.).)

analyses, it is unsurprising that their opinions largely parrot those of other experts, which is an independent reason to exclude them. For example, Dr. Levy conceded that his “evidence” on heavy metals consists of his review of plaintiffs’ other experts’ reports and that he cannot offer an independent opinion about heavy metals “because that wasn’t part of my analysis.”³⁹ Similarly, Dr. Moorman did not perform analyses related to heavy metals’ presence in talc herself; rather, she relies on Dr. Crowley’s report (which is on fragrances, not heavy metals), and performed no analysis other than reviewing the IARC monograph as the basis for her opinion that such metals may be carcinogenic.⁴⁰ Having performed no independent analysis of their own, the Court should not allow these experts to be “the mouthpieces” of plaintiffs’ other experts. *See, e.g., Dura*, 285 F.3d at 614.⁴¹

³⁹ (5/8/24 Levy Dep. 127:5-128:6; *see also, e.g.*, Dep. of Sarah Kane (“1/25/19 Kane Dep.”) 133:23-135:2, Jan. 25, 2019 (Ex. 36 to Davidson Decl.) (conceding that she largely relied on plaintiffs’ other experts in this area); 1/25/19 Krekeler Dep. 25:11-22 (testifying that he defers to environmental and medical experts on whether heavy metals cause any disease); Dep. of Patricia G. Moorman (“1/25/19 Moorman Dep.”) 119:10-123:12, Jan. 25, 2019 (Ex. 37 to Davidson Decl.) (testifying that she is relying on Dr. Crowley’s report (which is on fragrances, not heavy metals).)

⁴⁰ (Moorman Rep. at 3, 7, 35; 1/25/19 Moorman Dep. 119:10-123:12.)

⁴¹ These experts’ opinions also largely do not depend on the presence of heavy metals (or fragrances) in the Products or such components being potentially carcinogenic. For example, plaintiffs’ expert Michele Cote, Ph.D., M.P.H. admits that such references are unnecessary to her opinion. (3/21/24 Cote Dep. 147:7-17.) Dr. Smith-Bindman admitted the same. (2/7/19 Smith-Bindman Dep. 313:18-25.)

B. Fragrances

Plaintiffs' primary expert on fragrances is Dr. Crowley, who concludes that the fragrances added to the Products "may contribute" to their "potential carcinogenicity." Thirteen experts who have no expertise on this topic and did not undertake their own, independent analysis blindly adopt Dr. Crowley's conclusion.⁴² For example:

- Dr. Kane states that "[f]or purposes of my opinions, I have reviewed and relied upon Dr. Crowley's report regarding the fragrance chemical constituents in Johnson & Johnson talcum powder products."⁴³
- Dr. Levy testified that he references Dr. Crowley's opinions about fragrances in his report but cannot offer an independent opinion about fragrances "because that wasn't part of my analysis."⁴⁴
- Dr. Smith-Bindman "reviewed the expert report from Dr. Crowley that concludes that some of these chemicals may contribute to the

⁴² (The primary portions of plaintiffs' experts' reports containing opinions regarding fragrances are: Carson Rep. at 6-8; Clarke-Pearson 3d Am. Rep. at 7-8, 13; Cote Am. Rep. at 11-12, 91; Kane Rep. at 29, 36; Levy 2d Am. Rep. at 16-18; Moorman Rep. at 35; Plunkett 3d Am. Rep. at 24-25, 77-78; Sage Am. Rep. at 6-7; Singh Rep. at 60; Smith Rep. at 19, 21-22; Smith-Bindman 3d Am. Rep. at 4, 11, 15; Zelikoff Rep. at 12, 27; Wolf 3d Am. Rep. at 13, 21; McTiernan 3d Am. Rep. at 88.)

⁴³ (See Kane Rep. at 5; *see also e.g.*, Zelikoff Rep. at 12 (citing Dr. Crowley's opinion and "concur[ring]" without independent analysis); *see also* Clarke-Pearson 3d Am. Rep. at 7-8 (citing Crowley report for proposition that the "fragrance chemicals in talcum powder" contain "carcinogens"); Plunkett 3d Am. Rep. at 25 (citing Dr. Crowley's report for the proposition that "over 70%" of the fragrances "have been linked with some level or irritant hazard"); Singh Rep. at 14, 60, 68 (stating that the "fragrance ingredients . . . are known or suspected carcinogens" and citing Dr. Crowley's report).)

⁴⁴ (5/8/24 Levy Dep. 127:5-128:6.)

inflammatory response, toxicity, and potential carcinogenicity of Johnson's & Johnson's talcum powder products. I concur with his opinion."⁴⁵

These experts made it clear that they have simply adopted Dr. Crowley's conclusions regarding fragrances—i.e., that they did not independently validate those opinions.⁴⁶ In so doing, these witnesses have effectively conceded both that they are not experts on the purported carcinogenicity of fragrances and that they are “simply ‘parrot[ing] the ideas of’ Dr. Crowley. *Torain*, 2023 WL 174952, at *5. Their conclusory claims on fragrances should therefore be excluded.

II. PLAINTIFFS' EXPERTS' HEAVY METAL OPINIONS ARE UNRELIABLE.

To the extent any plaintiffs' experts attempt to base their heavy metal opinions on a methodology, their efforts fail for two primary reasons. *First*, there is no scientific support for the notion that exposure to these metals causes ovarian cancer; indeed, none of plaintiffs' experts was able to point to a single study

⁴⁵ (3d Am. Rep. at 15; *see also, e.g.*, Smith Rep. at 19 (similar); Carson Rep. at 6 (similar); Moorman Rep. at 35 (similar); Levy 2d Am. Rep. at 19 (similar); 9/23/21 Sage Dep. 207:11-13 (Dr. Sage also testified that he is not an expert in fragrances); Wolf 3d Am. Rep. at 12-13 (similar); McTiernan 3d Am. Rep. at 88 (similar); Sage Am. Rep. at 6-7 (similar).)

⁴⁶ (9/23/21 Sage Dep. 290:6-291:3 (Dr. Sage testified that he performed no independent assessment of fragrances and did not even read the entirety of Dr. Crowley's report); Cote Am. Rep. at 11-12 (similar); 3/21/24 Cote Dep. 144:24-147:6 (Dr. Cote testified that she simply summarized Dr. Crowley's report and performed no independent analysis or even read defendants' experts' opinions).)

suggesting such an association. And *second*, none of plaintiffs' experts identifies: (1) the amount of exposure to heavy metals that would purportedly render them toxic; or (2) the amount of heavy metals to which a talc user would be exposed (or even know the concentration of heavy metals found in the Products).

A. There Are No Scientific Studies Linking Heavy Metal Exposure To Ovarian Cancer.

First, plaintiffs' experts cannot point to a single study connecting exposure to any heavy metal allegedly found in talc with ovarian cancer.

For example, Dr. Zelikoff's report lists a litany of "adverse effects on human health" resulting from exposure to nickel, chromium and cobalt, but none of those purported adverse effects is related to ovarian cancer.⁴⁷ Moreover, Dr. Zelikoff conceded that she is not aware of *any* studies that discussed the potential of *any* of these heavy metals to cause ovarian cancer or that have examined whether these metals have any effect on human ovarian cells.⁴⁸ Drs. Carson and Plunkett also could not point to studies connecting these heavy metals to ovarian cancer.⁴⁹

⁴⁷ (Zelikoff Rep. at 8-10, 9-10.)

⁴⁸ (1/21/19 Zelikoff Dep. 294:14-295:4.)

⁴⁹ (See, e.g., 1/19/19 Carson Dep. 300:20-24; 12/19/18 Plunkett Dep. 271:24-274:16; see also, e.g., Dep. of Judith K. Wolf ("9/13/21 Wolf Dep.") 414:13-415:13, Sept. 13, 2021 (Ex. 38 to Davidson Decl.) ("Q. What evidence do you have that any heavy metal contained in Johnson's Baby Powder causes endometrioid ovarian cancer? A. I don't know that there's any evidence, but I don't know that anybody's ever studied specifically those heavy metals, chromium, nickel, cobalt, which can be carcinogenic, cause ovarian cancer

(cont'd)

Plaintiffs have argued that the dearth of scientific studies is of no concern because of risk assessments undertaken by various agencies suggesting that some heavy metals may be carcinogenic.⁵⁰ But none of these assessments references ovarian cancer. For example, plaintiffs have pointed to an IARC monograph that identifies the lung, nasal cavity and paranasal sinuses as tumor sites for chromium VI and nickel, but the monograph does *not* identify the ovary as a potential target organ.⁵¹ Similarly, the Agency for Toxic Substances and Disease Registry

specifically. They're carcinogenic.") (objection omitted); *see also* Dep. of Sonal Singh ("1/16/19 Singh Dep.") 298:24-299:10, Jan. 16, 2019 (Ex. 39 to Davidson Decl.) (stating that he was "not aware of studies that link [heavy metals] directly to ovarian cancer"); Dep. of Daniel L. Clarke-Pearson ("2/4/19 Clarke-Pearson Dep.") 290:19-291:10, Feb. 4, 2019 (Ex. 40 to Davidson Decl.) (testifying that he does not "think that anybody's ever studied" whether exposure to heavy metals can cause ovarian cancer); 1/25/19 Moorman Dep. 122:12-19 (similar testimony); 1/9/19 Smith Dep. 376:14-19 (similar testimony); 1/25/19 Kane Dep. 141:14-23 (similar testimony).)

⁵⁰ (PSC's Mem. in Resp. & Opp'n to Defs.' Mot. to Exclude Pls.' Experts' Ops. Regarding Alleged Heavy Metals & Fragrances in Johnson's Baby Powder & Shower-To-Shower ("Pls.' 2019 Opp'n") at 9-10, May 29, 2019 (ECF 9885).)

⁵¹ (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 100C, Arsenic, Metals, Fibres, and Dust ("IARC 2012 Monograph") at 151-167, 169-218 (2012) (Ex. 41 to Davidson Decl.); *see also* Straif, *A Review of Human Carcinogens—Part C: Metals, Arsenic, Dusts, and Fibres*, 10 *Lancet* 453, 453 (2009) (Ex. 42 to Davidson Decl.).) Although IARC's ultimate *classifications* are "not target organ oriented," that is so because its mission is to identify carcinogens rather than "classify exposures according to carcinogenicity for specified target organs." Merletti, *Target Organs for Carcinogenicity of Chemicals and Industrial Exposures in Humans: A Review of Results in the IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans*, 44 *Cancer Res.* 2244, 2244 (1984) ("Merletti 1984") (Ex. 43 to Davidson Decl.)

(cont'd)

(“ATSDR”) and the National Toxicology Program (“NTP”)—other government agencies referred to by plaintiffs—never suggest that exposure to any of these heavy metals is capable of causing ovarian cancer.⁵² It is axiomatic that different

(emphasis added). In other words, a classification by IARC that a substance is carcinogenic merely reflects IARC’s view that there is “*at least one* target organ for which sufficient evidence of carcinogenicity is judged to exist.” *Id.* (emphasis added). Such a classification cannot be construed as a finding that the substance in question is carcinogenic to *all* organs given that “cancers affecting different organs and systems in humans have different causes.” *Id.*

⁵² For example, according to the ATSDR, “[t]he primary targets” of exposure to chromium (VI) “appear to be the respiratory tract, gastrointestinal tract, hematological system, liver, and kidneys.” ATSDR, *Toxicological Profile for Chromium (CAS#: 7440-47-3)*, at 287 (Sept. 2012), <https://www.atsdr.cdc.gov/ToxProfiles/tp7.pdf>. The ATSDR similarly specifies the existing studies on the health effects of nickel by *organ system* and *exposure route*. ATSDR, *Toxicological Profile for Nickel (CAS#: 7440-02-0)*, at 264 (Figure 6-1) (Aug. 2023) (Draft for Public Comment), <https://www.atsdr.cdc.gov/ToxProfiles/tp15.pdf>. According to the NTP document cited by plaintiffs, with regard to exposure to chromium (VI), “[t]he data for cancer at sites *other than the lung and sinonasal cavity were unclear*.” NTP, *Report on Carcinogens, Fifteenth Edition: Chromium Hexavalent Compounds (CAS No. 18540-29-9)*, at 1 (2021), <https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/chromiumhexavalentcompounds.pdf> (emphasis added). Similarly, the data relevant to the NTP’s examination of cobalt compounds “were from studies primarily evaluating lung cancer . . . esophageal cancer and other cancers of the respiratory and upper digestive (aerodigestive) tract.” NTP, *Report on Carcinogens, Fifteenth Edition: Cobalt-Related Exposures (CAS No. 7440-48-4)*, at 2 (2021), <https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/chromiumhexavalentcompounds.pdf>. And with regard to the alleged carcinogenicity of nickel compounds, the NTP observed that epidemiological studies indicated an “elevated risk” of lung and nasal cancer. NTP, *Report on Carcinogens, Fifteenth Edition: Nickel Compounds and Metallic Nickel*, at 1 (2021), <https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/chromiumhexavalentcompounds.pdf>.

types of cancer have different etiologies, and an expert cannot rely on studies involving one form of cancer to conclude that an exposure causes a different type of cancer.⁵³

Notably, Dr. McTiernan conceded in another case “that an analysis of cancer risk where all cancers are combined[] ‘is not the accepted method of considering associations of carcinogens with specific cancer type risk.’” *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1233 (S.D. Fla. 2022) (citation omitted); *see also, e.g., In re Deepwater Horizon Belo Cases*, No. 19-963 et al., 2024 U.S. Dist. LEXIS 112817, at *33 (N.D. Fla. June 25, 2024) (“[S]tudies identifying an association between an exposure and acute skin irritation cannot be reliably used to conclude an association exists between that exposure and chronic dermatitis or eczema”); *In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, MDL No. 3043, 2023 U.S. Dist. LEXIS 224899, at *110 (S.D.N.Y. Dec. 18, 2023) (excluding expert who “combines studies on ASD, ADHD, and a variety of symptom outcomes without adequately explaining his basis for doing so or confronting the complexities created by this conflation”); *Allen v. Pa. Eng’g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996) (while the plaintiffs’ experts had pointed to evidence “that suggests a connection between EtO exposure and human lymphatic

⁵³ Plaintiffs’ experts themselves acknowledge as much. (1/4/19 Crowley Dep. 212:14-213:2; 1/25/19 Kane Dep. 143:16-145:1; 1/9/19 Smith Dep. 346:8-347:18; 1/19/19 Carson Dep. 179:8-24.)

and hematopoietic cancers,” such evidence was not “probative on the causation of brain cancer”). As such, the Zantac MDL court found that Dr. McTiernan’s practice of “commingl[ing] [of] data” from different types of cancer “depart[ed] from conventional science,” *In re Zantac*, 644 F. Supp. 3d at 1233, which is exactly what she and plaintiffs’ other experts have done in this litigation.

Some plaintiffs’ experts speculate more generally that the purported heavy metals in cosmetic talc could contribute to ovarian carcinogenicity by causing inflammation.⁵⁴ As a threshold matter, the theory that inflammation can cause ovarian cancer is, at best, a hypothesis, for all the reasons set forth in defendants’ Biological Plausibility brief, filed separately. In any event, there is no evidence that any of the alleged metals found in talcum powder can even cause inflammation of the ovaries. As plaintiffs’ genetics expert Dr. Levy put it, there is

⁵⁴ (See, e.g., Smith-Bindman 3d Am. Rep. at 15; Smith Rep. at 19; Levy 2d Am. Rep. at 18; Zelikoff Rep. at 12-13.) In addition, plaintiffs’ experts fail to properly interpret the literature they cite because they ignore that chromium exists in different forms. While studies have shown that chromium (VI) may be a carcinogen, there is no reason to think (let alone actual evidence) that chromium (VI) is present in talc, as opposed to chromium (III), which is the most prevalent form of chromium and is found naturally in the environment. (See, e.g., Zelikoff Rep. at 9.) Indeed, for example, Dr. Krekeler admits he did not test to determine the valence state of the chromium. (Krekeler Rep. at 36.) Plaintiffs attribute the lack of opinions as to the form of chromium allegedly found in talc to defendants’ own testing procedures, which plaintiffs say “failed to distinguish between chromium (III) and chromium (VI).” (See Pls.’ 2019 Opp’n at 29.) But the notion that exposure to alleged chromium in the Products can cause ovarian cancer is “an issue on which *plaintiff[s]*” bear “the burden of proof.” *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 786 (3d Cir. 1996) (emphasis added).

no “direct evidence for heavy metal contribution to the inflammation process.”⁵⁵

Likewise, Dr. Zelikoff conceded that “there are no studies that demonstrate” that the heavy metals purportedly found in talc cause inflammation in the ovary.⁵⁶

For these reasons alone, plaintiffs’ experts’ heavy metal opinions should be excluded.

B. Plaintiffs’ Experts Fail To Address Dose.

Plaintiffs’ experts’ opinions on the alleged relationship between heavy metal exposure and ovarian cancer are also inadmissible because plaintiffs’ experts ignore the question of dose. *See, e.g., Pinares v. Raytheon Techs. Corp.*, No. 19-14831, 2023 WL 2661521, at *3-5 (11th Cir. Mar. 28, 2023) (excluding expert opinion because expert ignored fundamental requirement that experts must specify how much exposure to a toxic chemical is “too much”); *In re Deepwater Horizon Belo Cases*, 2024 U.S. Dist. LEXIS 112817, at *17 (excluding general causation opinions ignoring that “[s]cientific knowledge of the harmful level of exposure to a chemical is a minimal fact necessary to sustain the plaintiff’s burden in a toxic tort

⁵⁵ (Dep. of Shawn Levy (“1/11/19 Levy Dep.”) 353:15-17, Jan. 11, 2019 (Ex. 44 to Davidson Decl.).)

⁵⁶ (1/21/19 Zelikoff Dep. 291:3-24.) Even if there were evidence for a pro-inflammatory effect of any of the heavy metals allegedly at issue, it would remain to be shown that the Products contained heavy metals in sufficient quantities to produce that inflammatory effect—which, as further detailed in the next section, no plaintiffs’ expert has even attempted to show.

case”); *In re Acetaminophen*, 2023 U.S. Dist. LEXIS 224899, at *89 (excluding epidemiologist’s opinion on dose-response who “does not grapple with a key issue in the underlying studies: none were able to record the actual dosages taken by pregnant women”); *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 548 (W.D. Pa. 2003) (“the concept of ‘dose-response’ is a fundamental premise of toxicology”).

Although plaintiffs’ experts agree that a dose-response relationship is critical to assessing toxicity,⁵⁷ none of them identified the supposed threshold for exposure to various heavy metals sufficient to cause ovarian cancer—or even inflammation,⁵⁸ or quantified, even in rough terms, the amount of heavy metals to which genital talc users were purportedly exposed,⁵⁹ let alone the amount of heavy

⁵⁷ As Dr. Zelikoff acknowledged at her deposition, “dose as well as frequency, duration, time of exposure . . . all . . . contribute to the toxicity of an agent.” (1/21/19 Zelikoff Dep. 262:11-15.) Indeed, “most materials could be hazardous if too much is consumed or if the exposure is too great.” (1/4/19 Crowley Dep. 129:7-9.) *See also Reference Manual on Scientific Evidence* (“RMSE”) (3d ed. 2011), at 636 (“Even water, if consumed in large quantities, can be toxic.”).

⁵⁸ (See, e.g., 1/21/19 Zelikoff Dep. 282:10-24 (“Q. What are the exposure levels of these metals necessary to have biologic plausibility of ovarian cancer? A. As far as biological plausibility of these metals, these metals are -- unless there are particular standards for a particular metal, nothing is really established for what it would take for nickel to cause ovarian cancer. However, the ability of these metals to produce inflammation are very, very low levels. And if they produce inflammation, then they have the potential to go on to produce cancer. And many of these metals do.”).)

⁵⁹ (See, e.g., 1/19/19 Carson Dep. 175:6-11, 176:5-10 (agreeing that he did not
(cont’d)

metals that would reach a woman's ovary through perineal talc use.⁶⁰

To compensate for their inability to identify a dose-response relationship, some of plaintiffs' experts claim that *any* exposure to heavy metals, no matter how trivial, can cause ovarian cancer.⁶¹ Courts across the country, however, have rejected this so-called "any exposure" approach to causation as unscientific and unreliable under *Daubert*. See, e.g., *McMunn v. Babcock & Wilcox Power Generation Grp., Inc.*, 869 F.3d 246, 270-71 (3d Cir. 2017) ("Even were this [any-exposure] evidence substantively permissible under Pennsylvania law, it would fail to be admissible under *Daubert*"); *Pelton v. John Crane, Inc.*, No. 21-4316, 2024 U.S. Dist. LEXIS 16865, at *13 (N.D. Ill. Jan. 31, 2024) ("cumulative dose" and "each and every exposure" theor[ies]" are "inadmissible under Federal Rules of

know the amounts of heavy metals in the Products and that he did not assess a woman's exposure to heavy metals through use of talcum powder); 12/19/18 Plunkett Dep. 263:24-264:1 ("No, I have not done a -- a calculation of a potential dose with perineal application for any of the heavy metals."); 2/4/19 Clarke-Pearson Dep. 292:6-10 ("Q. How, if at all, did you factor the dose [of] fragrances and heavy -- or trace heavy metals into your analysis of the potential relationship between those compounds and ovarian cancer? A. I didn't factor [dose] in.")

⁶⁰ (See, e.g., 1/19/19 Carson Dep. 169:17-23 ("Q. Do you have any idea how much of these metals, if any, reaches a woman's ovaries each time they use talc? A. I can't tell you how much, but I can tell you that some does . . .").)

⁶¹ (See, e.g., *id.* 171:6-21 (asserting that even a single particle of chromium, cobalt or nickel "within the microenvironment of the inflammatory process . . . is contributing to the carcinogenic potential" of talc); 1/21/19 Zelikoff Dep. 319:23-321:1, 321:21-322:21 (claiming that, in her "professional opinion," exposure to even one particle of cobalt, chromium or nickel, either inhaled or applied perineally, could cause inflammation in the ovaries).)

Evidence 702 and *Daubert*”); *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 679-80 (6th Cir. 2011) (“[I]t is well-settled that the mere existence of a toxin in the environment is insufficient to establish causation without proof that the level of exposure could cause the plaintiff’s symptoms.”); *In re W.R. Grace & Co.*, 355 B.R. 462, 476 (Bankr. D. Del. 2006) (“The use of the no safe level or linear ‘no threshold’ model for showing unreasonable risk ‘flies in the face of the toxicological law of dose-response’”) (citation omitted).

Plaintiffs’ experts’ “any exposure” theory is even more problematic here because it ignores that many of the trace heavy metals allegedly found in talc are, as plaintiffs’ experts acknowledge, also commonly found in the environment, including in food, drinking water or the air; indeed, chromium, cobalt and nickel are all recognized as essential nutrients in the United States.⁶² As the Third Circuit

⁶² (1/19/19 Carson Dep. 169:24-170:9; *see also, e.g.*, 2/7/19 Smith-Bindman Dep. 140:4-8.) *See also, e.g.*, EPA, *National Primary Drinking Water Regulations*, <https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations> (last updated June 13, 2024) (The EPA’s National Primary Drinking Water standard for total chromium (including chromium [VI]) is 0.1 mg/L); EPA, *Chromium in Drinking Water*, <https://www.epa.gov/sdwa/chromium-drinking-water> (last updated Feb. 23, 2024) (“Chromium-3 is an essential human dietary element. It is found in many vegetables, fruits, meats, grains, and yeast.”); ATSDR, *Public Health Statement: Cobalt* (CAS#: 7440-48-4) (Apr. 2004), <https://www.atsdr.cdc.gov/ToxProfiles/tp33-c1-b.pdf> (“Cobalt is widely dispersed in the environment in low concentrations. You may be exposed to small amounts of cobalt by breathing air, drinking water, and eating food containing it.”; “The average person consumes about 11 micrograms of cobalt a day in their diet.”); ATSDR, *Toxicological Profile for Nickel* (CAS#: 7440-02-0), at 1 (Aug. 2023)

(cont’d)

has explained, where exposure to a particular substance is common because the substance is a “‘constituent element’ of our environment,” plaintiffs seeking to prove causation must “demonstrate [that] they have been exposed” to the substance “to a greater extent than anyone else, i.e., that their exposure levels exceeded the normal background level.” *In re TMI Litig.*, 193 F.3d 613, 644, 659 (3d Cir. 1999) (citations omitted), *amended in nonmaterial part*, 199 F.3d 158 (3d Cir. 2000).

Plaintiffs have also argued that a quantitative dose assessment is not required because this litigation involves “mixtures containing known carcinogens” such that one can just “*assume* that there are additive effects among the constituents, or ‘potential interactions among the components.’”⁶³ But whether the case involves *mixtures* containing purportedly hazardous substances does not alter the analysis. *See Johnson v. Arkema, Inc.*, No. 09-107, 2010 U.S. Dist. LEXIS 148982, at *43-44 (W.D. Tex. Dec. 16, 2010) (rejecting claim that chemicals plaintiff was exposed to are “dose additive”; although expert “would ‘expect’ them to be . . . he hasn’t ‘quantitated’ it”; “the dose additive argument is not reliable”), *aff’d in relevant*

(Draft for Public Comment), <https://www.atsdr.cdc.gov/ToxProfiles/tp15.pdf> (“Thus, the public is exposed to nickel daily from many sources including air, food, water, and products containing nickel such as cooking utensils and jewelry.”).

⁶³ (Pls.’ 2019 Opp’n at 15 (emphasis added) (citing EPA, *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures*, at App. A-7 (Aug. 2000), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=4486).

part and rev'd in non-relevant part, 685 F.3d 452 (5th Cir. 2012) (per curiam); *see also Williams v. Mosaic Fertilizer, LLC*, No. 14-1748, 2016 U.S. Dist. LEXIS 192236, at *33-34 (M.D. Fla. June 24, 2016) (“Dr. Mink’s failure to perform dose-response calculations for any of the constituents” of the emissions and fugitive dust “render his general causation opinions speculative and unreliable.”), *aff’d*, 889 F.3d 1239 (11th Cir. 2018).

In sum, plaintiffs’ experts’ “any exposure” theory is not based on scientific evidence, but rather on their “lack of information” about whether the amounts of the metals alleged to be in the Products exceed any level of exposure sufficient to create a genuine risk to human health. *Anderson v. Ford Motor Co.*, 950 F. Supp. 2d 1217, 1224 (D. Utah 2013). Accordingly, these opinions are speculative and unreliable under both *Daubert* and Rule 702 and should be excluded.

III. DR. CROWLEY’S OPINION THAT THE FRAGRANCES USED IN THE PRODUCTS CONTRIBUTE TO THE DEVELOPMENT OF OVARIAN CANCER LACKS FOUNDATION.

Dr. Michael Crowley claims that fragrances used in the Products contribute to causing ovarian cancer. But Dr. Crowley consistently misunderstood or misapplied the sources he relied upon to draw his conclusions, cannot point to scientific literature suggesting a link between exposure to the fragrance substances in the Products and ovarian cancer, and has zero evidence that the dose of the fragrance components, which together account for less than one percent of the

overall product, is capable of contributing to the supposed carcinogenicity of talc. Accordingly, these opinions do not pass muster under Rule 702 or *Daubert*.

A. Dr. Crowley Has No Scientific Evidence Linking Fragrance Exposure To Ovarian Cancer.

Rule 702 requires a district court to confirm that expert testimony is genuinely scientific. *In re Paraquat Prods. Liab. Litig.*, MDL No. 3004, 2024 WL 1659687, at *4 (S.D. Ill. Apr. 17, 2024), *appeal filed*; *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002) (“expert testimony to be reliably based upon scientific methods”), *aff’d*, 68 F. App’x 356 (3d Cir. 2003). In other words, an “expert’s opinions must be based on the methods and procedures of science”—i.e., “the expert must have ‘good grounds’ for his or her belief.” *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 656 (D.N.J. 2008) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994)). When an expert’s conclusions do not “reliably flow from the facts known to the expert and the methodology used,” those conclusions must be excluded from trial. *Magistrini*, 180 F. Supp. 2d at 595, 603-08 (citation omitted) (excluding expert whose application of his methodology was unreliable).

Dr. Crowley’s opinions lack “good grounds” for several reasons.

First, as set forth above, courts have made clear that expert opinions are unreliable when there is no “association in the literature between an exposure and” the *specific* disease at issue. *In re Deepwater Horizon Belo Cases*, 2024 U.S. Dist.

LEXIS 112817, at *34; *see also* *Burleson v. Tex. Dep't of Crim. Just.*, 393 F.3d 577, 586 (5th Cir. 2004) (applying this principle to cancers); *see also, e.g., Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 145-46 (1997) (district court properly excluded expert opinion that plaintiff's exposure to PCBs contributed to his cancer where the studies underlying the expert's opinion "did not suggest a link between the increase in lung cancer deaths and the exposure to PCB's"); *Nat'l Bank of Commerce v. Associated Milk Producers, Inc.*, 22 F. Supp. 2d 942, 983 (E.D. Ark. 1998) (excluding expert testimony on causation where experts could not point to any "scientific studies or medical literature that show[ed] any correlation between exposure to [the purported carcinogen] and laryngeal cancer").

These same principles compel exclusion of Dr. Crowley's fragrance opinions. Dr. Crowley has been offered to support plaintiffs' theory that the fragrances added to the Products "contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products."⁶⁴ But as Dr. Crowley repeatedly made clear during his deposition, there are *no* studies linking *any* of the fragrances used in the Products to ovarian cancer in humans.⁶⁵ Plaintiffs' other

⁶⁴ (Crowley Rep. at 11.)

⁶⁵ (1/4/19 Crowley Dep. 114:9-15; *see also id.* 199:16-19 ("I am not aware of an epidemiological study substantiating the causation of ovarian cancer from the so-called fragrance chemicals."); *id.* 234:5-20 (confirming that none of the fragrances listed in Table 7 of his report had "been studied for ovarian cancer in humans").) At his deposition, Dr. Crowley repeatedly testified that he lacked

(cont'd)

experts were similarly unable to identify anything in the medical literature connecting any of the fragrances used in the Products to ovarian cancer.⁶⁶

Plaintiffs have previously argued that studies demonstrate a link between some of the fragrance chemicals and toxicity and/or carcinogenicity in humans, but none of the studies purports to tie even a single fragrance in the Products to *ovarian* cancer (and some do not even tie them to any cancers). Rather, as plaintiffs expressly recognized, these other studies examined potential effects on human skin cells and other tissues.⁶⁷ Particularly in light of Dr. Crowley's own

knowledge about the effect of fragrance ingredients on human ovaries because it is "unethical" to do "those kind of studies" in humans. (*See, e.g., id.* 222:4-7, 282:9-12.) But animal studies have identified several agents (not present in the fragrances at issue here) that exhibit "clear or some evidence of carcinogenicity" in the ovaries of animal models. *See* NTP, *Organ Sites with Neoplasia*, <https://cebs.niehs.nih.gov/organsites/> (last updated May 8, 2024).

⁶⁶ (*See, e.g.,* 1/21/19 Zelikoff Dep. 313:21-314:3 (conceding that none of the chemicals used in fragrances has been reported in the medical literature to induce inflammation in the ovaries); 12/19/18 Plunkett Dep. 275:13-25 (no scientific evidence indicating that the fragrances were capable of causing ovarian cancer); 2/4/19 Clarke-Pearson Dep. 289:12-290:8 (stating that he was not aware of any scientific literature indicating that the fragrances in the Products could cause ovarian cancer or inflammation); Dep. of Rebecca Smith-Bindman ("2/8/19 Smith-Bindman Dep.") 320:21-25, Feb. 8, 2019 (Ex. 45 to Davidson Decl.) ("Q. There have been no fragrance chemicals, to your knowledge, that have been found in a study to be associated with ovarian cancer, correct? A. I -- I know of no -- no such exploration.") (objection omitted).)

⁶⁷ (*See* Pls.' 2019 Opp'n at 53 (referencing study examining purported cytotoxic effect of lavender oil on human skin cells *in vitro*); *id.* (noting that the 1995 study of cresols examined dermal and oral exposure); *id.* at 54 (referencing study observing "menstrual disorders and hormonal disturbances").)

recognition that an agent can cause one type of cancer but not another,⁶⁸ these studies say nothing about whether the fragrances in the Products are capable of causing the “*specific* disease from which [plaintiffs] suffer[.]” *Sutera v. Perrier Grp. of Am. Inc.*, 986 F. Supp. 655, 662 (D. Mass. 1997) (emphasis added).

Second, Dr. Crowley’s reliance on studies using Chinese hamster ovary cells cannot save his opinions.⁶⁹ As a threshold matter, courts routinely “caution against direct extrapolation from cellular . . . studies to humans.” *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 466, 477 (E.D. Pa. 2014). This is because *in vitro* studies “necessarily remove the cells from the dynamic metabolic context in which the human body actually processes chemical compounds.” *In re Accutane Prods. Liab.*, 511 F. Supp. 2d 1288, 1294-95 (M.D. Fla. 2007); *Wade-Greaux v. Whitehall Lab ’ys, Inc.*, 874 F. Supp. 1441, 1469 (D.V.I. 1994), *aff’d*, 46 F.3d 1120 (3d Cir. 1994); *see also, e.g., In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 429-35 (S.D.N.Y. 2005) (finding that cell

⁶⁸ (1/4/19 Crowley Dep. 212:14-213:2.)

⁶⁹ (See *id.* 217:12-218:5 (“[W]e have animal studies that show toxicity issues with cells in animal models, like Chinese hamster ovary cell models”); *id.* 117:10-12 (asserting that benzyl alcohol was found to be “cytogenic in Chinese hamster ovary cells”); *id.* 221:20-222:2 (“Q. Is d-Limonene a genotoxic material? A. I don’t believe it’s been classified as that, but cytotoxicity against Chinese hamster ovary cells indicates that it could be against ovaries, at least in this animal model.”).)

studies of rats were not “a reliable basis for extrapolating to the liver of a living human”).

Dr. Crowley compounds the difficulties in extrapolating from cell studies by relying on *animal* cellular studies. *See In re Acetaminophen*, 2023 U.S. Dist. LEXIS 224899, at *35-36 (“[F]or animal studies to be admissible to prove causation in humans, there must be good grounds to extrapolate from animals to humans, just as the methodology of the studies must constitute good grounds to reach conclusions about the animals themselves.”) (citation omitted). Although Dr. Crowley agreed that “it’s possible that an ingredient can cause or contribute to the development of cancer or a cancer in an animal but not in humans,”⁷⁰ he never explains the basis for his extrapolations from the animal cell studies he cites—none of which is supported by human data. This is not surprising; after all, none of the studies, including the in vitro studies using hamster ovary cells, shows an increase in rates of *ovarian cancer*. *See, e.g., Perry v. Novartis Pharms. Corp.*, 564 F. Supp. 2d 452, 466 (E.D. Pa. 2008) (expert conclusion that exposure to drug could cause non-Hodgkin lymphoma not reliable where studies showed that animals developed lymphoma or non-lymphoma tumors but not specifically non-Hodgkin lymphoma). The female reproductive and immune systems, by contrast, involve a number of different types of cells and include natural repair mechanisms for

⁷⁰ (*Id.* 212:22-213:2.)

foreign substances. Thus, while *in vitro* studies like the ones relied upon by Dr. Crowley may “suggest[] that there might be a need to study the agent in humans,” they cannot support an opinion that any fragrance ingredient is toxic in humans. *Wade-Greaux*, 874 F. Supp. at 1469. This is particularly true given that—as Dr. Crowley admits—a number of factors affect how a body responds to fragrances, including the “route of administration” and “the kinetics of how [the fragrances are] metabolized, distributed, and eliminated.”⁷¹

Notably, the relevant literature makes clear that Chinese hamster ovary cells are commonly used in mutagenicity assays because they “exhibit a routine cloning efficiency higher than 80% in a reasonably well-defined medium.”⁷² While data obtained from Chinese hamster ovary cell assays may “indicate a likelihood or potential of the test chemical to be a mutagen or carcinogen for humans . . . a direct correlation between mutagenicity in the CHO/HGPRT assay and in animals or humans is not fully established.”⁷³ Therefore, data from Chinese hamster ovary cells should not be “a basis for classifying chemicals either as animal or human

⁷¹ (*Id.* 214:5-22.)

⁷² Hsie, *The Use of Chinese Hamster Ovary Cells to Quantify Specific Locus Mutation and to Determine Mutagenicity of Chemicals. A Report of the Gene-Tox Program*, 86(2) *Mutat. Res.* 193, 196 (1981) (Ex. 46 to Davidson Decl.).

⁷³ *Id.* at 205.

mutagens/carcinogens or as nonhazardous” or to “establish acceptable exposure levels.”⁷⁴

Plaintiffs have argued that it is not ethically possible to test for the carcinogenicity and toxicity of chemicals on human ovaries—studies can only be performed on animals. But any ethical limitations on conducting human studies do not relieve plaintiffs’ experts of their burden of “connect[ing] the dots” from the studies they cite to human ovarian cancer—a burden they did not come close to carrying. *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 837 (7th Cir. 2015) (although “[t]hese studies are unavailable because of the ethical and moral concerns of introducing toxins to children,” the experts failed “to connect the dots from the studies” they cited “to the illnesses endured by the children”).

Third, Dr. Crowley’s claim that the Products are “not in compliance with governmental and industry standards”⁷⁵ further undermines the reliability of his opinions. Dr. Crowley searched materials available in the “public domain” to perform a “regulatory review” of the fragrances in the Products.⁷⁶ But many of Dr. Crowley’s conclusions are inconsistent with—or contrary to—the information set forth in the sources he cites. For example:

- Dr. Crowley asserts that four fragrance ingredients—styrene, coumarin,

⁷⁴ *Id.*

⁷⁵ (Crowley Rep. at 11.)

⁷⁶ (*Id.* at 18; 1/4/19 Crowley Dep. 110:23-111:15, 360:7-10.)

eugenol and D-limonene—are “potential carcinogens” based on IARC’s Group 3 classification.⁷⁷ But Dr. Crowley admits that IARC’s Group 3 classification means that a particular substance “is ***not classifiable as to its carcinogenicity to humans***,” meaning there is inadequate evidence that the substance causes cancer in humans—and, to the contrary, there may be “strong evidence that the mechanism of carcinogenicity in experimental animals ***does not*** operate in humans.”⁷⁸

- Dr. Crowley claims that benzophenone was “removed from use in foods by FDA due to histiocytic sarcoma observed in ovaries and uterus, higher incidences of kidney tumors and leukemia in animal studies, and in vivo estrogenic activity.”⁷⁹ But the 2006 NTP study that Dr. Crowley cites in support of this statement only concluded that the histiocytic sarcomas they observed “were highly invasive” and affected “[m]ultiple organs,” but did not conclude that benzophenone can cause ovarian cancer.⁸⁰ As the FDA noted in discussing this study, histiocytic sarcomas are “rarely reported in humans” and “were found only at dose levels that induced overt toxicity” in rodents—no increase in tumor incidence was reported at the lowest test dose. Food Additive Regulations; Synthetic Flavoring Agents and Adjuvants, 83 Fed. Reg. 50,490, 50,495 (Oct. 9, 2018). Moreover, the FDA did not decide to remove benzophenone due to any purported concern about human health effects. To the contrary, the FDA concluded that “benzophenone is ***unlikely*** to induce tumors in humans at current use levels as a synthetic flavoring substance and adjuvant in food.” *Id.* (emphasis added).
- Dr. Crowley claims that p-cresol is “possibly carcinogenic,” pointing to a 1990 report published by the U.S. Environmental Protection Agency

⁷⁷ (See Crowley Rep. at 64.)

⁷⁸ IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble, at 36 (2019), <https://monographs.iarc.who.int/wp-content/uploads/2019/07/Preamble-2019.pdf> (second emphasis added). (Crowley Rep. at 13, 21, 70-71, 121.) Plaintiffs also have expressly conceded that defendants are “correct that coumarin, eugenol, and D-limonene” “have IARC Group 3 classifications.” (Pls.’ 2019 Opp’n at 43.)

⁷⁹ (Crowley Rep. at 48 (citations omitted); *see also id.* at 65.)

⁸⁰ Rhodes, *Carcinogenesis Studies of Benzophenone in Rats and Mice*, 45(5) Food Chem. Toxicol. 843, 848-49 (2007) (Ex. 47 to Davidson Decl.).

(“EPA”).⁸¹ In that report, the EPA grouped p-cresol as a Classification C carcinogen—a “possible human carcinogen”—based on “increased incidence of skin papillomas in mice.”⁸² In a more recent review that Dr. Crowley ignored, however, the Agency for Toxic Substances and Disease Registry concluded that, based on the EPA’s updated criteria for carcinogenicity, p-cresol “fall[s] in the category of chemicals for which there is ‘inadequate information to assess carcinogenic potential.’”⁸³

- Dr. Crowley states that “Musk ketone is suspected of being a carcinogen, and has been classified as a Category 3 carcinogen by the Scientific Committee on Health and Environmental Risks (SCHER) in Europe.”⁸⁴ SCHER classified musk ketone as a Category 3 carcinogen—i.e., a substance with limited evidence of carcinogenic effect—based on data related to a similar substance.⁸⁵ The SCHER panel determined that the classification of musk xylene was “a borderline case since an increase in liver tumours in the highly sensitive B6C3F1 mouse is considered of little relevance for human hazard assessment.”⁸⁶ Notably, the European Union’s Institute for Health and Consumer Protection recognized that musk ketone is commonly used in fragrances and determined there was “no need for risk

⁸¹ (Crowley Rep. at 12.)

⁸² EPA, *Integrated Risk Information System, 4-Methylphenol; CASN 106-44-5*, at 4 (1993), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0302_summary.pdf.

⁸³ ATSDR, *Toxicological Profile for Cresols (CAS#: 1319-77-3)*, at 12 (Sept. 2008), <https://www.atsdr.cdc.gov/ToxProfiles/tp34.pdf>. Plaintiffs also have conceded that the most recent assessment of pre-cresol “concluded that there is **inadequate** information to assess [that fragrance’s] carcinogenic potential.” (Pls.’ 2019 Opp’n at 47 (emphasis added).)

⁸⁴ (Crowley Rep. at 12; *see also id.* at 48.)

⁸⁵ European Commission Health & Consumer Protection Directorate-General, Sci. Committee on Health & Env’t Risks (SCHER), *Opinion on Classification of Musk Ketone 3* (Jan. 2006), https://ec.europa.eu/health/archive/ph_risk/committees/04_scher/docs/scher_o_022.pdf.

⁸⁶ *Id.*

reduction measures” to reduce exposures below current levels.⁸⁷

As these examples make plain, Dr. Crowley engaged in a haphazard inquiry to arrive at conclusions that are not supported by the data on which he claims to rely. Plaintiffs have previously argued that these are “simple misunderstanding[s]” and “any mistakes in Dr. Crowley’s report should be addressed in cross examination, not result in the wholesale exclusion of his opinions.”⁸⁸ But that is “the precise type of weight vs. admissibility distinction the recent amendment to Rule 702 aimed to correct.” *West v. Home Depot U.S.A., Inc.*, No. 21-1145, 2024 U.S. Dist. LEXIS 76437, at *10-11 (N.D. Ill. Apr. 26, 2024) (rejecting argument that “inaccuracies” in causation opinion should be addressed through cross-examination) (citation omitted); *accord In re Onglyza (Saxagliptin) & Kombiglyze (Saxagliptin & Metformin) Prods. Liab. Litig.*, 93 F.4th 339, 347, 348 n.7 (6th Cir. 2024) (“Rule 702’s recent amendments were drafted to correct some court decisions incorrectly holding ‘that the critical questions of the sufficiency of an expert’s basis, and the application of the expert’s methodology, are questions of

⁸⁷ See European Chemicals Bureau, CAS No: 81-14-1, EINECS No. 201-328-9, 4'-Tert-Butyl-2',6'-Dimethyl-3',5'-Dinitroacetophenone (*Musk Ketone*) *Summary Risk Assessment Report* 27 (2005), <https://echa.europa.eu/documents/10162/e6a84904-118b-447a-8766-f7bda48f7ce0>.

⁸⁸ (Pls.’ 2019 Opp’n at 48, 49 n.187.)

weight and not admissibility.”) (citation omitted).⁸⁹ For this reason, too, Dr. Crowley’s opinions do not satisfy the “minimum requirements of reliability” and should be excluded. *Lithuanian Commerce Corp. v. Sara Lee Hosiery*, 179 F.R.D. 450, 459-60 (D.N.J. 1998).

B. Dr. Crowley’s Failure To Analyze Dosage Further Renders His Opinions Inadmissible.

Dr. Crowley’s fragrance opinions are also inadmissible because he fails to identify the level of exposure to fragrance ingredients that would be necessary to cause harm and determine whether the Products contained ingredients above that level. Dr. Crowley does not know the exposure levels at which the fragrances can allegedly cause any cancer (let alone, ovarian cancer) or even the amount of any

⁸⁹ See also, e.g., *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 284 (4th Cir. 2021) (the amendment clarifies that it is an “abdication of [the] gatekeeping role” to punt “critical” reliability and methodology questions to lay juries) (citation omitted); *In re Deepwater Horizon Belo Cases*, 2024 U.S. Dist. LEXIS 112817, at *50-52 (“The amendment was motivated by the Advisory Committee’s observation that in a number of federal cases . . . judges did not apply the preponderance standard of admissibility to Rule 702’s requirements of sufficiency of basis and reliable application of principles and methods, instead holding that such issues were ones of weight for the jury[,]’ which is ‘an incorrect application of Rules 702 and 104(a).”) (citation omitted); *In re Paraquat*, 2024 WL 1659687, at *4 nn. 8 & 9 (“The Advisory Committee thus appears to have found that courts had erroneously admitted unreliable expert testimony based on the assumption that the jury would properly judge reliability”); *Johnson v. United States*, No. 21-2851, 2024 U.S. Dist. LEXIS 53513, at *9 n.7 (E.D.N.Y. Jan. 16, 2024) (“The amendment was aimed at courts that had erroneously held that ‘the critical questions of the sufficiency of an expert’s basis, and the application of the expert’s methodology, are questions of weight and not admissibility.’”) (citation omitted).

particular fragrance ingredient in the Products.⁹⁰ Dr. Crowley’s attempts to defend this fundamental shortcoming in his opinion all lack merit.

First, in lieu of identifying true levels of exposure ostensibly associated with ovarian cancer, Dr. Crowley attempts to rely on regulatory thresholds identified for some of the fragrances at issue. For example, Dr. Crowley states that, “[o]f the 141 fragrance chemicals in the product, 23 fragrances have a Category 5 Restriction”—meaning that the International Fragrance Association (“IFRA”) has set exposure limits to those fragrances.⁹¹

But regulatory thresholds are set according to policy and precautionary principles; they are no substitute for scientific evidence establishing dangerous levels of exposure. *See, e.g., Henderson v. Lockheed Martin Corp.*, No. 21-1363, 2024 U.S. Dist. LEXIS 72330, at *20 (M.D. Fla. Mar. 18, 2024) (“[R]esearch agencies like IARC are, understandably, focused on protecting public health and recommending protective standards, rather than evaluating causation from an expert standpoint in the litigation context.”) (citing *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1249 (11th Cir. 2005)) (“[T]he procedures commonly used in

⁹⁰ (*See, e.g.*, 1/4/19 Crowley Dep. 309:12-20 (does not know exposure levels); *id.* 225:14-19 (does not know the concentration of d-Limonene in the Products); *id.* 232:23-233:4 (does not know the concentration of benzaldehyde in the Products); *id.* 252:19-253:3 (does not know the concentration of styrene in the Products).)

⁹¹ (Crowley Rep. at 39.)

‘risk assessment’ for the purpose of establishing public health guidelines that represent ‘acceptable’ exposure levels for large populations are often . . . of marginal relevance to estimating ‘causation’”) (quoting David L. Eaton, *Scientific Judgment and Toxic Torts—A Primer in Toxicology for Judges and Lawyers*, 12 J.L. & Pol’y 5, 34 (2003)). And in any event, as already noted, Dr. Crowley has no evidence that use of the Products would result in exposure that exceeds these thresholds. To the contrary, he expressly disclaimed such knowledge.⁹²

Second, Dr. Crowley blames his methodological deficiencies on the fact that he was not provided with “information to know how much of each fragrance chemical was present in the composition.”⁹³ This rationalization fails for multiple reasons. As a threshold matter, an expert cannot simply speculate because he lacks data, *Williams*, 2016 U.S. Dist. LEXIS 192236, at *33-34; rather, the burden is on **plaintiffs** to demonstrate that Dr. Crowley’s opinions are “based on sufficient facts or data.” Fed. R. Evid. 702(b). In any event, the premise of Dr. Crowley’s

⁹² (1/4/19 Crowley Dep. 209:10-210:2; *see also, e.g., id.* 329:2-331:2 (stating that although there are “a bunch of” fragrance chemicals that have exposure restrictions, he was unable to “make a judgment as to whether [the fragrance] present in baby powder exceeds” the regulatory threshold or not).)

⁹³ (*Id.* 124:3-13; *see also id.* 200:24-201:5 (“Q. You have not been able to do a dose response analysis. Correct? A. Again, I couldn’t do it because I didn’t have the information from J&J, I suppose, to enable doing that.”) (objection omitted).)

complaint that he did not have the data he needed is wrong. A number of documents that were produced to plaintiffs—including documents that Dr. Crowley cites in his report—list the maximum concentration of fragrance ingredients in the Products. For example, the formulation documentation shows that Johnson’s Baby Powder contained a maximum of 0.22 percent fragrance ingredients,⁹⁴ and other documents produced in discovery revealed the constituent ingredients of the fragrance.⁹⁵ While Dr. Crowley complained that the documents he saw did not include units,⁹⁶ units are not necessary to understand exposure levels. Even without units, it is easy to discern that each ingredient is necessarily less than 0.22% of ingredients in each exposure to talc (since 0.22% is the total amount of all fragrance ingredients combined). And the numbers provided for each fragrance ingredient, even without units, allows the reader to roughly estimate what portion of that 0.22% is made up of each ingredient because the numbers are relative—the maximum amount of the first ingredient is listed as 25.0, for example, while maximum amounts of other ingredients are 10.0, 5.0, 1.0 or 0.1. Minimum amounts are also provided. Thus, for a given volume of product, it would be possible to estimate the maximum possible exposure to each fragrance

⁹⁴ (See JNJALC000891091.)

⁹⁵ (Exs. 1-3 to Response Email from Richard T. Bernardo to Chris Tisi, Oct. 16, 2018 (collectively, Ex. 48 to Davidson Decl.).)

⁹⁶ (1/4/19 Crowley Dep. 124:8-13.)

ingredient by assuming the maximum amount of that ingredient and the minimum amount of each of the other ingredients and then calculating the maximum relative portion of the ingredient at issue.⁹⁷

That is what defendants' toxicology expert Dr. Paul Nony did, a straightforward calculation that led him to conclude that the maximum concentration of the fragrant chemicals are multiples less than the IFRA standards.⁹⁸ For example, with respect to amyl cinnamal, Dr. Nony readily determined that the percentage of the chemical of 0.0022 was 2,545 times less than the restriction set by the IFRA that the chemical not comprise more than 0.056% of a product. Dr. Nony performed the same straightforward assessment with respect to each of the other fragrances.⁹⁹ Notably, these same assessments were set forth in the reports of defendants' experts Dr. Tuttle and Dr. Moore and were not

⁹⁷ To the extent Dr. Crowley or plaintiffs really had difficulty analyzing these documents, they could have sought clarification in discovery.

⁹⁸ (Rep. of Paul A. Nony ("Nony Rep.") at 105, App. D (IFRA Fragrance Table), May 28, 2024 (Ex. 49 to Davidson Decl.)) Dr. Crowley's failure to even attempt to approximate any woman's exposure to fragrance chemicals is especially problematic in light of the mega-doses used in the animal studies upon which he relies. (1/4/19 Crowley Dep. 272:15-273:5.) *See Wade-Greaux*, 874 F. Supp. at 1454 ("High dosage animal studies cannot be relied upon to determine whether a substance is teratogenic in humans in therapeutic doses."); *Perry*, 564 F. Supp. 2d at 472 (excluding causation opinions where plaintiffs' experts "fail[ed] to address the disparity in the dosages [plaintiff] received and the dosages in the animal studies on which they rely").

⁹⁹ (Nony Rep. at App. D (IFRA Fragrance Table).)

challenged in plaintiffs' original *Daubert* motions, effectively conceding their reliability.¹⁰⁰ Simply put, Dr. Crowley's failure to quantify the level of exposure to fragrance ingredients necessary to cause harm was the result of his own unwillingness to do so rather than incompleteness in documents provided to plaintiffs. And the fact that Dr. Crowley did not amend his report to analyze dose-response based on this data after defendants pointed out its availability in 2019,¹⁰¹ only cements its unreliability.

Third, at his deposition, Dr. Crowley also attempted to excuse his failure to conduct a dose-response assessment by suggesting that "some of the[] fragrance chemicals are genotoxic."¹⁰² According to Dr. Crowley, a dose-response assessment is unnecessary because genotoxins only "need one molecule for there to be an increased risk."¹⁰³ But Dr. Crowley's report only identifies some ingredients as potentially genotoxic; thus, his genotoxicity excuse for ignoring

¹⁰⁰ (See generally PSC's Mot. to Exclude Ops. of Defs.' Toxicology Experts Brooke T. Mossman, M.S., Ph.D., Kelly S. Tuttle, Ph.D. & H. Nadia Moore, Ph.D., May 7, 2019 (ECF 9739-1); Rep. of Kelly Scribner Tuttle ("Tuttle Rep.") at 53, Feb. 25, 2019 (Ex. 50 to Davidson Decl.); Rep. of H. Nadia Moore ("Moore Rep.") at 71, Feb. 25, 2019 ("Moore Rep.") (Ex. 51 to Davidson Decl.).)

¹⁰¹ (Defs.' 2019 Mot. at 51.)

¹⁰² (1/4/19 Crowley Dep. 124:14-16.)

¹⁰³ (*Id.* 124:16-20; see also *id.* 125:20-23 (explaining that genotoxic materials "don't have a threshold" because "[o]ne molecule is enough to cause an increased risk").)

dose does not apply to the vast majority of ingredients he addresses.¹⁰⁴ And even if it were established that a particular fragrance were genotoxic, that fact would not be sufficient to classify the material as carcinogenic.¹⁰⁵ In any event, Dr. Crowley is simply wrong in asserting (without support) that dose is irrelevant to genotoxicity.¹⁰⁶

For these reasons, too, Dr. Crowley's opinions about a relationship between the fragrances in the Products and ovarian cancer should be excluded.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the Court exclude the opinions proffered by plaintiffs' experts regarding alleged heavy metals and fragrances.

¹⁰⁴ In his report, Dr. Crowley asserted that "[s]everal chemicals in the fragrance mixture used by J&J" had demonstrated "genotoxicity" in cell and animal studies but also acknowledged that the studies "[we]re not definitive that the same effects would be observed in humans." (Crowley Rep. at 21.)

¹⁰⁵ See, e.g., NTP, No. 389, *Toxicology and Carcinogenesis Studies of Sodium Azide (CAS No. 26628-22-8) in F344/N Rats (Gavage Studies)* (1991), https://ntp.niehs.nih.gov/sites/default/files/ntp/htdocs/lt_rpts/tr389.pdf (noting that sodium azide is genotoxic in assays but does not cause cancer).

¹⁰⁶ See, e.g., *RMSE* at 636 (noting that whether a substance can cause harm is, in all circumstances, "a question of dose").

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Respectfully submitted,

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